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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

Applicant: William E. KLUNK *et al.*
Title: ***BENZOTHAZOLE DERIVATIVE COMPOUNDS,
COMPOSITIONS AND USES***
Appl. No.: 10/645,847
Filing Date: 8/22/2003
Examiner: Dameron Levest JONES
Art Unit: 1618
Confirmation
Number: 8143

APPELLANTS' REPLY BRIEF UNDER 37 C.F.R. § 41.41

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Under the provisions of 37 C.F.R. § 41.41 and in response to the Examiner's Answer that was mailed on September 3, 2008 ("Answer"), Appellants submit this Reply Brief. The filing due date for filing this response is November 3, 2008, and so this brief is timely filed.

Accompanying this brief is Appellants' request for an Oral Hearing. The due date for filing the request also is November 3, 2008, making it timely under 37 C.F.R. § 41.47.

ARGUMENT

In maintaining an obviousness-type double-patenting rejection of claim 1, the Examiner's Answer embodies two interwoven and wholly erroneous themes. First, the PTO justified its rejection of claim 1 based upon mere overlap in scope with claim 4 of cited U.S. Patent No. 7,270,800 ("the '800 patent"). Second, the PTO impermissibly tied its obviousness analysis to knowledge of disclosure not only in the '800 patent specification but also in Appellants' specification.

I. Mere Overlap in Claim Scope Does Not Give Rise to an Obviousness-type Double Patenting Concern

The Examiner's Answer eschews an obviousness analysis in favor of a simple determination of whether any overlap exists between a prior-patented species and the presently claimed genus.¹ Where, as here, a double-patenting rejection is based upon obviousness, the correct rule of law requires the PTO to engage in the factual inquiries that are set forth in *Graham v. John Deere*.² Additionally, "it remains necessary to identify some reason that would have led a chemist to modify a known compound in a particular manner to establish prima facie obviousness of a new claimed compound."³

The Answer committed the PTO to an argument that stacks possibility upon possibility in asserting that compounds Nos. 4, 8, 12, 16, 20, and 39 in cited claim 4 fall within the scope of present claim 1 and, from the Examiner's perspective, thereby render the latter obvious. First, the PTO asserted that all of these compounds "like the instant invention, have halogens in the R2 position as required by instant claim 1."⁴ Second, the Answer stated without elaboration that it would have been obvious to replace a halogen in that position with a radiolabeled halogen.⁵ In

¹ Answer at page 8, lines 5-7.

² See *In re Braat*, 937 F.2d 589, 19 USPQ2d 1289 (Fed. Cir., 1991); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); Appellant's Brief on Appeal at page 9, lines 14-17.

³ *Takeda Chemical Industries, Ltd. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350, 1356, 83 U.S.P.Q.2d 1169, 1174 (Fed. Cir. 2007) (internal citations omitted; citing *In re Deuel*, 51 F.3d 1552, 1558 (Fed.Cir.1995); emphasis added).

⁴ Answer at page 8, lines 7-9.

⁵ See *id.* at page 8, line 9-12.

the words of the PTO, the “obviousness” of the replacement “stems from” the prescription in cited claim 4 to replace an atom with one of several recited radiolabeled halogens.⁶

The error in this analysis is evident from the fact that the PTO’s assertion is unallied with any apparent rationale for why the skilled person would select just these compounds for modification in the specific manner propounded by the PTO. Thus, cited claim 4 does not specify what position(s) in the compounds depicted therein are amenable to substitution with radiolabeled halogens. In cited compound 39, for instance, a fluoro substituent no more suggests its replacement than does the presence of a hydrogen ‘substituent’ elsewhere in the molecule suggest *its* substitution with a radiolabeled halogen.

The Answer also fails to address Appellants’ point, underscored in their Appeal Brief, that the above-discussed assertion by the PTO, even taken at face value, does not validate the PTO’s bald pronouncement that Appellants’ invention is obvious over patented claim 4.⁷ To the extent that an underlying principle is discernable in this regard, the PTO appears to apply a rule that would make a radiolabeled atom *per se* obvious over prior disclosure of a “cold” (non-labeled) version of the same atom. Suffice to say, Section 103 admits to no such “rule.” Thus, the PTO’s rejection at its heart manifests an unprincipled selection of cold fluoro- and iodo-substituted species to be modified such that the fluoro and iodo substituents, selected by yet a further separation from principle, are replaced by their radiolabeled isotopes.

II. The PTO Impermissibly Relied Upon the Disclosures of the ‘800 Patent and the Present Application

Appellants noted previously that the PTO had imbued the skilled artisan with impermissible knowledge of rejected claim 1.⁸ The PTO now obfuscates this legal error by mischaracterizing Appellants’ position as that of taking issue with the PTO’s reliance upon improper hindsight *reasoning*.⁹ Further, the PTO emphasizes that “reconstruction based upon

⁶ *Id.*

⁷ Appellant’s Brief on Appeal filed on June 19, 2008 at page 12, lines 7-8.

⁸ *Id.* at page 11, lines 17-23.

⁹ Answer at page 9, lines 4-5.

hindsight reasoning” is proper so long as it accounts for knowledge possessed by the skilled artisan at the time of invention, and not knowledge from appellants’ disclosure.¹⁰

Appellants never addressed such reasoning. Instead, they objected to the PTO’s ceding *knowledge* of claim 1 to the skilled artisan, in order to substantiate the obviousness-type double patenting rejection at issue.

The PTO also explicitly invokes a source of knowledge relating “[b]oth the compounds of the patented invention and [use of] the instant invention ... for the same purposes (i.e., imaging amyloid plaques).”¹¹ From the PTO’s exegesis, it is difficult to consider such “knowledge” as other than vital to the rejection:

Specifically, both inventions are used for the same purpose (i.e., detecting amyloid plaques) and both the instant invention and patented invention disclose compounds having radiohalogens in the R2 position.¹²

Whence this knowledge of purpose and use? The source must *not* be the ‘800 patent specification, for well-settled law prohibits the use of a patent’s disclosure as prior art in a double-patenting rejection.¹³

Limited exceptions permit resorting to the specification to illuminate claim terminology¹⁴ or to gauge support for a patent claim.¹⁵ Nothing about the present record could reasonably call either of these exceptions into play, however. That is, consulting the ‘800 patent specification to discover imaging uses or purposes is not necessary to understanding cited claim 4. Further, the PTO has made no case for needing to consult the ‘800 patent for claim-supporting disclosure. In any event, such disclosure would pertain to the *synthesis* of the compounds recited in claim 4, not to their use or purpose.

¹⁰ *Id.* at page 9, lines 6-10.

¹¹ Answer at page 8, lines 12-13.

¹² Answer at page 9, lines 13-15.

¹³ *General Foods Corp. v. Studiengesellschaft Kohle mbH*, 972 F.2d 1272, 1279, 23 USPQ2d 1839, 1846 (Fed. Cir. 1992).

¹⁴ See *Toro Co. v. White Consol. Indus., Inc.*, 199 F.3d 1295, 1299, 53 USPQ2d 1065, 1067 (Fed. Cir., 1999); *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1250, 48 USPQ2d 1117, 1122 (Fed. Cir., 1998).

Furthermore, rejected claim 1 is directed to compounds, as such, and to their pharmaceutically acceptable salts, hydrates, solvates, and prodrugs, respectively. Nothing in the claim speaks of imaging use or purpose.¹⁶

Claim 4 of the '800 patent likewise is directed to a method of synthesizing compounds. Thus, the claim provides no hint of the imaging use relied upon by the PTO.

For these reasons, the PTO's analysis should not have instilled the skilled artisan with knowledge of amyloid detection uses for the cited and claimed compounds, respectively. Stripped of such impermissible knowledge, the analysis reflected in the Examiner's Answer devolves to identifying mere overlap in claim scope and an unprincipled substitution with radiohalogens, as discussed above.

Because a showing of mere overlap in claim scope does not substantiate the PTO's stated position that pending claim 1 is obvious over cited claim 4, no double-patenting concern should pertain. Accordingly, Appellants respectfully urge the Board to reverse the PTO's rejection of claim 1.

Respectfully submitted,

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¹⁵ See *In re Vogel*, 422 F.2d 438, 441-42, 164 USPQ 619, 622 (CCPA 1970).

¹⁶ For reasons not clear to Appellants, the PTO cites to Appellants' specification in order to establish its understanding that "the patented invention does not exclude radiohalogens in the R² position." Answer at page 8, line 17 to page 9, line 3. The reference to the specification is gratuitous, however: a straightforward reading of claim 1 requires no interpretation to understand that the definition of R² explicitly contemplates radiohalogens.